Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Cardiovascular and Renal Drugs Advisory Committee
July 28, 2008
Hilton Washington DC/Silver Spring, Maryland Ballroom
8727 Colesville Road, Silver Spring MD

DRAFT AGENDA

8:00 a.m.	Call to Order Introduction of Committee	Robert Harrington, M.D. Chair, CRDAC
	Conflict of Interest Statement	Elaine Ferguson, M.S. Designated Federal Official, CRDAC

The committee will discuss new drug application (NDA) 22-449, binodenoson injectable, lypholized solid 250 mcg vial, King Pharmaceuticals Research and Development, Inc., for the proposed indication: short acting coronary vasodilator for use as an adjunct to non-invasive myocardial perfusion imaging (MPI) tests to detect perfusion abnormalities in patients with known or suspected coronary artery disease (CAD).

8:10 a.m.	FDA Opening Remarks	Rafel (Dwaine) Rieves, M.D. Director Division of Medical Imaging and Hematology Products, CDER, OND, OODP
8:15 a.m.	Sponsor Presentations: Introduction and agenda	Eric Carter, PhD, MD Chief Science Officer, King Pharmaceuticals, Inc.
	Background information, efficacy and safety	TBD
	Biostatistical considerations	TBD
	Closing remarks	Eric Carter, PhD, MD Chief Science Officer, King Pharmaceuticals, Inc.
10:00 a.m.	Questions to the Sponsor	
10:30 a.m.	Break	

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10:45 a.m.	Clinical Summary of Safety and Efficacy Data	Libero Marzella, M.D., Medical Team Leader, Division of Medical Imaging and Hematology Products, CDER, OND, OODP
11:05 a.m.	Statistical Summary of Efficacy Data	Mark Levenson, Ph.D., Statistical Reviewer, Division of Biometrics, CDER, OTS
11:30 a.m.	Questions to presenters	
Noon	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Discussion of questions to committee	
3:30 p.m.	Break	
5:00 p.m..	Adjourn	